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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,507	11/08/2001	Brian Leyland-Jones	3298.1000-000	6118
21005	7590	05/04/2004	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			COUNTS, GARY W	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,507

Applicant(s)

LEYLAND-JONES ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/08/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, drawn to method and kit of determining CYP 1A2 phenotype.

Group II, claim(s) 17-32, drawn to method and kit of determine NAT1 phenotype.

Group III, claim(s) 33-48, drawn to method and kit of determining CYP 2D6 phenotype.

Group IV, claim(s) 49-64, drawn to method and kit of determining CYP 2E1 phenotype.

Group V, claim(s) 65-80, drawn to method and kit of determining CP 3A4 phenotype.

Group VI, claim(s) 81 drawn to a p-aminosalicylic acid derivative.

Group VII, claim(s) 82 drawn to a p-aminosalicylic acid metabolite derivative.

Group VIII, claim(s) 83 drawn to a caffeine derivative.

Group IX, claim(s) 84, 92 and 93 drawn to a 1,7-dimethylxanthine metabolite derivative and method of synthesizing a 1,7-dimethylxanthine derivative.

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Group X, claim(s) 85, 94 and 95 drawn to a 1,7-dimethyluric acid metabolite derivative and method of synthesizing a 1,7-dimethyluric acid derivative.

Group XI, claim(s) 86 drawn to a dextromethorphan derivative.

Group XII, claim(s) 87 drawn to a dextromethorphan metabolite derivative.

Group XIII, claim(s) 88 drawn to a chlorzoxazone derivative.

Group XIV, claim(s) 89 drawn to a chlorzoxazone metabolite derivative.

Group XV, claim(s) 90 drawn to a dextromethorphan derivative.

Group XVI, claim(s) 91 drawn to a dextromethorphan metabolite derivative.

The inventions listed as groups I – XVI do not relate to a single general inventive Concept under PCT Rule 13.1 because, under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons. Groups I – V are methods directed at determining different phenotypes (i.e. Group I, claims 1-16 CYP 1A2; Group II, claims 17-32 NAT1; Group III, claims 33-48 CYP 2D6; Group IV 49-64 CYP2E1; and Group V, claims 65-80 CYP 3A4). Groups VI – XVI are drawn to different derivatives. The methods of Groups I-V are not methods of making or methods of using the derivative of Groups VI-XVI but rather are methods of measuring the derivatives. Therefore, there are 5 different methods and 11 derivatives. Under Rule 13 Applicant is entitled to one product, one method of making and one method of using.

There are no special technical features tying the methods and the derivatives together.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

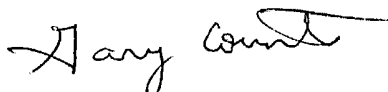
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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary W. Counts
Examiner
Art Unit 1641
April 27, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

04/30/04